UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	IR 6493-02	3786

28997 7590 01/11/2005

HARNESS, DICKEY, & PIERCE, P.L.C
7700 BONHOMME, STE 400
ST. LOUIS, MO 63105

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,127	ZICKER ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004 and 24 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39, 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Claim 39 is rejected under 35 U.S.C. 102(e) as being anticipated by Hamilton, 6,335,361 B1 .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment(s)

The following is responsive to Applicant's amendment and remarks received Aug. 24, 2004 and March 8, 2004.

Claims 40-43 are cancelled. New claims 44-47 are added. Claims 39, 44-47 are currently pending.

The previous claim objection and claim rejection under 35 USC 112, second paragraph, set forth on page 2 of the office action mailed Nov. 3, 2003 are withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(a) over Harper, WO 00/44375, set forth in paragraph 3 of the office action mailed Nov. 3, 2003 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) over Ames et al., set forth in paragraphs 6-7 of the office action mailed Nov. 3, 2003 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 103(a) set forth at paragraphs 8-11 of the office action mailed Nov. 3, 2003 are withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejection under 35 USC 102(e) over Hamilton, 6,335,361, set forth in paragraphs 4-5 of the office action mailed Nov. 3, 2003 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Nov. 3, 2003. Applicant's arguments will be addressed below.

Finally, Applicant's amendment necessitated new grounds of rejection, which are submitted below.

Claim Rejection(s)—35 USC 102 over Hamilton:

Applicant submits that claim 39 is not anticipated by the Hamilton references. Specifically, Applicant contends

"Hamilton discloses the treatment of cognitive disorders particularly those associated with aging using a combination of lipoic acid and l-carnitine. Among those mentioned is memory loss. But, this is specifically associated with individuals having unhealthy mitochondria, see col. 7, lines 14-17, areas which are specifically associated with lipoic acid, used in association with l-carnitine in Hamilton. There is nothing in Hamilton which associates memory loss and unhealthy mitochondria with the prevention or treatment of dogs and cats for increasing learning ability or inhibiting loss of learning ability."

Said arguments have been considered but are not found to be persuasive. The Examiner respectfully submits that the disclosed association of cognitive disorders with unhealthy mitochondria is not pertinent to the issue of patentability of the claimed method. From the standpoint of patentability the claimed method must distinguish over the prior art in terms of method steps. This is not the case here.

Hamilton discloses a method to improve memory in older pets as well as a method treat cognitive disorders such as age-related memory loss by administering a combination of the anti-oxidants carnitine and alpha-lipoic acid. The combination of anti-

oxidants may be added to pet food for administration to animals such as cats or dogs. Hamilton even discloses that the combination of anti-oxidants contributes to the improvement of mental acuity and inhibits age-related memory loss and provides improved memory in older subjects. Finally, Hamilton discloses that additional nutrients such as Vitamin E or C should be included as they are particularly important in older subjects. Applicant's claimed method steps are taught by the prior art. The Hamilton reference anticipates claim 39, and the rejection is respectfully maintained.

New Ground(s) of Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton, supra in view of Harper WO 00/44375. (references are already of record)

Hamilton as discussed above as well as in the office action mailed Nov. 3, 2003.

Hamilton does not specifically disclose the claimed mixture of anti-oxidants or the dosage amounts. However, the Examiner refers to Harper, which teaches a method for overcoming the problem of oxidative stress in a companion animal such as a dog or cat by increasing the plasma Vitamin E levels in the cat or dog. Specifically, a diet containing Vitamin C and Vitamin E are fed to senior (6.5- 12.5 years of age) dogs. Harper discloses that such a vitamin "cocktail" will prevent or treat a disorder (aging), which has a component of oxidative stress. Additionally, Harper teaches a method of feeding vitamin E separately to the companion animal in order to increase the Vitamin E levels in the plasma thereby overcoming the problem of oxidative stress. Please see the abstract, page 1, lines 18-21; page 13, line 12; page 16, lines 20-23; Example 19, pages 47-48.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Hamilton to specifically administer to the aged dog or cat a mixture of Vitamin E, C, l-carnitine and alpha lipoic acid because one of ordinary skill in the art would reasonably expect the combination of

these anti-oxidant compounds to counteract age-related memory loss and improve mental acuity. Even Hamilton suggests that additional administration of vitamin E or C would serve to enhance the treatment process by teaching that these anti-oxidants are particularly important in older subjects and should be included in the diet.

Finally, concerning the claimed dosage amounts, since Hamilton and Harper establish that effective amounts, i.e. dosage amounts, are necessary to the treatment of disorders/symptoms associated with aging and oxidative stress, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts of Hamilton and Harper such that the dosage amounts of the carnitine, vitamin E, vitamin C and alpha-lipoic acid are effective to inhibit oxidative stress or symptoms associated with aging in animals, thereby improving mental acuity and inhibiting age-related memory loss.

Conclusion

Claims 39, 44-47 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CDM

Dec. 27, 2004